A SYSTEM FOR MONITORING THE PHYSIOLOGIC PARAMETERS OF PATIENTS WITH CONGESTIVE HEART FAILURE

REFERENCE TO PREVIOUS APPLICATIONS

This application claims the benefit of United States Provisional Applications No. 60/415,537 filed on October 3rd, 2002, 60/415,538 filed on October 3rd, 2002, 60/416,406 filed on October 7th, 2002, 60/416,407 filed on October 7th, 200260/416,408 filed on October 7th, 2002, and 60/416,409 filed on October 7th, 2002.

FIELD OF THE INVENTION

The present invention relates generally to field of implantable medical devices for monitoring physiological parameters. More particularly, the invention relates to a system utilizing a telemetric implantable physiologic sensor for monitoring patients with Congestive Heart Failure and tailoring their medical management.

BACKGROUND OF THE INVENTION

Congestive heart failure (CHF) is a condition in which a damaged or overworked heart cannot pump adequately to meet the metabolic demands of the body and/or can do so only with an elevated ventricular diastolic pressure. CHF is a major health problem worldwide, affecting millions of patients and accounts for numerous hospitalizations. Overall, the cost of treating CHF is very high (billions of dollars annually) and involves numerous physician visits. From 1979 to 1999, CHF deaths increased 145% and hospital discharges increased 155%. Survival is poor with 20% dying within one year and only 50% of patients surviving more than 5 years.

The many patients suffering from this progressive, fatal disease tend to have an extremely poor quality of life and become increasingly unable to perform routine daily tasks.

Left ventricular (LV) filling pressure is a key factor in the progression of CHF. LV filling pressure represents the diastolic pressure at which the left atrium (LA) and left ventricle (LV) equilibrate, at which time the LV fills with blood from the LA. As the heart ages, cardiac tissue becomes less compliant, causing the LV filling pressure to increase. This means that higher pressures are required from the LA in order to fill the LV. The heart must compensate for this in order to maintain adequate cardiac output (CO); however, increasing the LA pressure strains the heart and over time irreversible alteration will occur.

Left Ventricular End Diastolic Pressure (LVEDP) and Mean Left Atrium Pressure (MLAP) (see Figure 1) are the primary factors physicians use to evaluate CHF patients. MLAP and LVEDP correspond directly with LV filling pressure and are easy for physicians to identify from LV pressure data. The physician's ultimate goal is to increase cardiac output (CO) while reducing LVDEP. Treatment methods include medications, lifestyle changes, pacemakers, and/or surgery.

The only current method for evaluating intracardiac pressures, including MLAP and LVEDP, is invasive, namely, a cardiac catheterization procedure. Catheterization, however, provides only a snapshot of pressure data, carries morbidity, and is expensive. Following diagnosis of congestive heart failure, physicians would prefer to noninvasively monitor heart condition on a continuing basis in order to optimize treatment. Currently, no technology exists that has this capability.

Furthermore, in certain cases, CHF is complicated by mitral stenosis. This is a very complex situation and requires significantly more precise and continuous pressure data. Atrial fibrillation can develop as a result of this condition, and catheterization to evaluate such cases is considerably more complex since pressure gradients across the mitral valve must also be

measured. Doppler echocardiography can be used to evaluate this condition; however, echocardiography again requires a specialized laboratory with specialized equipment and doesn't provide continuous measurements.

The treatment of cardiovascular diseases such as Chronic Heart Failure (CHF) can be greatly improved through continuous and/or intermittent monitoring of various pressures and/or flows in the heart and associated vasculature. Porat (U.S. Pat. No. 6,277,078), Eigler (U.S. Pat. No. 6,328,699), and Carney (U.S. Pat. No. 5,368,040) each teaches different modes of monitoring heart performance using wireless implantable sensors. In every case, however, what is described is a general scheme of monitoring the heart. The existence of a method to construct a sensor with sufficient size, long-term fidelity, stability, telemetry range, and biocompatibility is noticeably absent in each case, being instead simply assumed. Eigler, et al., come closest to describing a specific device structure although they disregard the baseline and sensitivity drift issues that must be addressed in a long-term implant. Applications for wireless sensors located in a stent (e.g., U.S. Pat. No. 6,053,873 by Govari) have also been taught, although little acknowledgement is made of the difficulty in fabricating a pressure sensor with telemetry means sufficiently small to incorporate into a stent.

SUMMARY OF THE INVENTION

The invention comprises a telemetric sensing system for monitoring physiologic parameters used to evaluate heart condition in CHF patients. The system includes an implantable sensor unit and a companion reader unit. The batteryless, wireless pressure sensor unit is implanted in any one of several locations in the heart (e.g. LA, LV, pulmonary artery (PA)). The implant may be delivered percutaneously (by catheter) or surgically. Once in place, the implant will be wirelessly interrogated with the reader.

Upon placement in the respective locations in the heart, the implant is capable of measuring and transmitting, in real time, any of various physiologic parameters including Left

Ventricular End Diastolic Pressure (LVEDP), Left Atrium Pressure, and Mean Left Atrium Pressure (MLAP). When desired, the implant is also able to monitor other parameters, including but not limited to blood flow and blood chemistry. Monitoring one or more of these parameters gives the physician several advantages:

- Enables earlier diagnosis of a failing heart
- Facilitates earlier intervention in the course of disease
- Facilitates ambulatory studies or applications
- Enables better tailoring of medications or other treatments and therapies to maximize cardiac output while reducing LVEDP
- Facilitates the identification of other complications from treatments or disease progression (e.g. weakening of other heart chambers)
- Gives faster feedback on the impact of medications and/or pacing changes on heart function.
- Facilitates defibrillator or pacemaker parameter optimization
- Decreases frequency and/or severity of hospitalization for CHF-related conditions through improved outpatient and home care monitoring
- Can be incorporated into an early warning system for serious conditions
- Lowers overall treatment costs
- Enables closed-loop medical delivery systems

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a graph of the expected waveforms for various pressure points within the heart.

Figure 2 is a block diagram of a magnetic telemetry based physiologic monitoring system based on a resonant scheme according to a preferred embodiment of the present invention.

Figure 3 is a block diagram of a magnetic telemetry based physiologic monitoring system based on a passive scheme according to an alternate embodiment of the present invention.

Figure 4 is a perspective view of a sensor implant incorporating a screw anchoring mechanism according to a preferred embodiment of the present invention.

Figure 5 is a side view of a sensor implanted in the atrial septum according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATE EMBODIMENTS OF THE INVENTION

The following description of preferred embodiments and methods provides examples of the present invention. The embodiments discussed herein are merely exemplary in nature, and are not intended to limit the scope of the invention in any manner. Rather, the description of these preferred embodiments and methods serves to enable a person of ordinary skill in the relevant art to make, use and perform the present invention.

In order to provide for the effective monitoring, management, and tailoring of treatments for congestive heart failure, the present invention provides a wireless sensing system. The system comprises two parts: an implantable pressure monitor which is securely anchored in a cavity of the heart; and a reader that both transmits power to and receives transmitted data from the implant. Data transmitted from the implantable device may include pressure, temperature, calibration data, identification data, fluid flow rate, chemical concentration, and/or other physiologic parameters.

In the preferred embodiment, the sensor transmits data corresponding to Left Ventricular End Diastolic Pressure (LVEDP) or Mean Left Atrium Pressure (MLAP). To accomplish this, the sensor is located such that it reads pressure in the left ventricle (LV) or Left Atrium (LA). Alternatively, pressures correlated to LVEDP or MLAP may be transmitted if the sensor is

located such that it reads pressures from the wedge position in the pulmonary artery. Furthermore, additional useful pressure data for monitoring CHF or other cardiovascular diseases may be obtained (by suitable location of the sensor) from pressures in the LA, aorta, right ventricle (RV), right atrium (RA), or pulmonary artery (PA). Note that the sensor may be located directly in the cavity whose pressure is being monitored, or it may be located in an intermediary structure, such as the atrial or ventricular septum, as long as communication with the parameter of interest is maintained.

In addition to LVDEP and MLAP, data useful to the physician and measurable with the described invention (in conjunction with appropriate mathematical algorithms) include, but are not limited to: dp/dt (pressure change over time) of the LV pressure, dp/dt of the LA pressure, dp/dt of the RV pressure, RVEDP, and mean RA pressure. Each of these may be measured and/or derived from pressures measured in the appropriate heart cavities.

For cases of CHF with mitral valve stenosis, a second sensor would be placed such that mitral valve gradient can be assessed (for example, one sensor in the LA and one in the LV). This allows assessment of the severity of mitral disease using the pressure gradient. Ultimately, this would provide critical information to help the physician decide whether to proceed with early valve surgery and/or balloon angioplasty/valvuloplasty.

The batteryless, wireless telemetry link is preferably implemented using either a resonant or passive, magnetically coupled scheme. A resonant device **101** (shown in Figure 2) is the simplest approach, and consists only of a packaged inductor coil **103** and capacitive pressure sensor **102**. Together, the two elements form a circuit that has a specific resonant frequency. At that resonant frequency, the circuit presents a measurable change in magnetically coupled impedance load to an external coil. Because the resonant frequency is a function of the coil inductance **103** and the sensor capacitance **102,** as pressure changes the

resonant frequency changes as well. An external reader **104** is able to determine pressure by monitoring the frequency at which the coil antenna **105** impedance changes.

The preferred communication scheme for the present invention, shown in Fig. 3, is based on magnetic telemetry. Devices that have on-board circuitry but still receive their operating power from an external source (i.e., are batteryless) are referred to as passive devices **201** (shown in Figure 3). Without an external reader present, the implant device **201** lays passive and without any internal means to power itself. When a pressure reading is desired, the reader device **202** is brought into a suitable range to the implant. In this case the external reader **202** uses an alternating magnetic field to induce a voltage in the implant. When sufficient voltage has been induced in the implant **201**, a rectification circuit **203** converts the alternating voltage on the receiver coil **204** into a direct voltage that can be used by the electronics **205** as a power supply for signal conversion and communication. At this point the implant **201** can be considered alert and, in the preferred embodiment, also ready for commands from the reader. The maximum achievable distance is mostly limited by the magnetic field strength necessary to turn the implant on. This telemetry scheme has been proven and used extensively in the identification and tracking industry (e.g., implantable RF ID technology from Texas Instruments or Digital Angel) with a great deal of acceptance and success.

Once the direct voltage in the implant has been established for the circuit operation, a number of techniques may be used to convert the sensor output into a form suitable for transmission back to the reader device. In the preferred embodiment, a capacitive pressure sensor **206** and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do suffer in this

application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

As those skilled in magnetic telemetry are aware, a number of modulation schemes are available for transmitting data via magnetic coupling. The preferred schemes include but are not limited to amplitude modulation, frequency modulation, frequency shift keying, phase shift keying, and also spread spectrum techniques. The preferred modulation scheme may be determined by the specifications of an individual application, and is not intended to be limited under this invention.

In addition to the many available modulation techniques, there are many technologies developed that allow the implant to communicate back to the reader the signal containing pressure information. It is understood that the reader device may transmit either a continuous level of RF power to supply the implant's needed energy, or it may pulse the power allowing temporary storage in a battery or capacitor device. Similarly, the implant **201** of Fig. 3 may signal back to the reader **202** at any interval in time, delayed or instantaneous, during reader RF (Radio Frequency) transmission or alternately in the absence of reader transmission. The implant **201** may include a single coil antenna **204** for both reception and transmission, or it may include two antennas, one each for transmission **204** and reception **221**. There are many techniques for construction of the reader coil **219** and processing electronics known to those skilled in the art. The reader **202** may interface to a display, computer, or other data logging devices **220**.

The electronic circuit may consist of a receiving inductor coil **204**, rectification circuitry **203**, signal conditioning circuitry **211**, and signal transmission circuitry **212**.

A large number of possible geometries and structures are available for receiver coil and known to those skilled in the art. The coil conductor may be wound around a ferrite core to

enhance magnetic properties, deposited on a flat rigid or flexible substrate, and formed into a long/skinny or short/wide cylindrical solenoid. The conductor is preferably made at least in part with a metal of high conductivity such as copper, silver, gold. The coil may alternately be fabricated on implantable sensor substrates. Methods of fabrication of coils on the sensor substrate include but not limited to one or more or any combination of the following techniques: sputtering, electroplating, lift-off, screen printing, and/or other suitable methods known to those skilled in the art.

The rectification circuitry **203** outputs a constant voltage level for the other electronics from an alternating voltage input. Efficient realizations of such circuitry are standard electronic techniques and may include full bridge diode rectifiers in the preferred embodiment. This rectification circuitry may include a capacitor for transient energy storage to reduce the noise ripple on the output supply voltage. This circuitry may be implemented on the same integrated circuit die with other electronics.

The signal conditioning circuit **211** processes an output signal from the sensor **206** and prepares it for transmission to an external receiving and/or analyzing device. For example, many pressure sensors output a capacitance signal that may be digitized for radio frequency (RF) transmission. Accordingly, the signal conditioning circuit **211** places the output signal of the sensor into an appropriate form. Many different signal conditioning circuits are known to those skilled in the art. Capacitance to frequency conversion, sigma delta or other analog to digital conversion techniques are all possible conditioning circuits that may be used in a preferred embodiment.

The signal transmission circuitry **212** transmits the encoded signal from the signal conditioning circuitry for reception by an external reader. Magnetic telemetry is again used for this communication, as the transmission circuitry **212** generates an alternating electromagnetic

field that propagates to the reader **202**. Either the same coil **204** is used for signal reception and for transmission, or alternately a second coil **221** is dedicated for transmission only.

A third option, particularly useful for (but not limited to) situations in which long-term data acquisition without continuous use of the readout unit is desirable, is to implement the sensor using an active scheme. This approach incorporates an additional capacitor, battery, rechargeable battery, or other power-storage element that allows the implant to function without requiring the immediate presence of the readout unit as a power supply. Data may be stored in the sensor and downloaded intermittently using the readout unit as required.

The implantable sensor may be physically realized with a combination of any of several technologies, including those using microfabrication technology such as Microelectromechanical Systems (MEMS). For example, capacitive and piezoresistive pressure sensors have been fabricated with MEMS technology. A hermetic sensor package may be formed from anodically bonded layers of glass and silicon (doped or undoped). Anchoring provisions may be incorporated directly into such a hermetic package, or they may alternately be added with an additional assembly step (e.g. as shown in Figure 4). An example of this would be insertion of the package into a molded plastic or metal shell that incorporates anchoring provisions. Possible anchoring methods include those conventionally used for cardiac pacing leads, such as screws or tines, as well as septal occluder schemes. Many such packaging schemes are known to those familiar with the art, and the present description should not be construed as limiting.

In addition to the basic implant-and-reader system, a number of other embodiments of the technology can be realized to achieve additional functionality. The system may be implemented as a remote monitoring configuration, including but not limited to home monitoring, which may include but not limited to telephone based, wireless communication based, or web-

based (or other communication means) delivery of information received from the implant by the reader to a physician or caregiver.

The system may be implemented as a closed-loop pacing/ICD (Implantable Cardioverter Defibrillator) tuning system, in which sensor data is fed to a patient pacemaker for tailoring of pacing/ICD function. The implanted sensor **101**, **201**, may be directly interrogated by the pacing/ICD unit (i.e. without requiring an intermediate reader unit). It may also be interrogated by the pacing/ICD unit, but with an additional, external unit solely for transmitting power to the implant. Alternatively, the sensor data may first be transmitted to an external reader and then re-transmitted to the pacing/ICD unit. Finally, the system may be configured such that both an external reader and the pacing/ICD unit may interrogate and/or power the sensor. (Sonbol add claims related to this P)

A closed-loop drug delivery system may also be envisioned. Data from the implanted sensor is fed directly to a drug delivery device (which may or may not be implanted, and may or may not be an integral part of the implanted sensor). This approach would allow continuous adjustment of medications for CHF-related conditions with minimal physician intervention.

Implanted sensor data may be used as feedback for a LA to RA unidirectional valve, which can be used to prevent pulmonary edema. LA decompression is accomplished by allowing blood to flow directly from the LA to the RA, thus reducing the pressure in the LA and the pulmonary bed.

The implantable sensor can be any suitable miniature sensor adapted to detect and/or monitor various physiological parameters. For example, the sensor can comprise a pressure sensor, a temperature sensor, a flow sensor, a velocity sensor, or a sensor adapted to measure specific chemistries such as gas content (e.g., $O2$ and $CO2$) and glucose levels. Various specific examples of these types of miniature sensors are known to those skilled in the art, and

any one or more of these suitable sensors can be utilized in the sensor module of the present invention. While the specific type of sensor(s) chosen will depend on the application of the implantable system, the sensor(s) should be of a sufficiently small size in order to facilitate placement within a catheter for delivery and implantation.

To limit the risk of thrombogenesis, the preferred embodiment has limited protrusion of volume into the blood stream (particularly in the left side of the heart), as both shape and size are factors in thrombogenesis. Another shell may be overmolded or preformed to house the glass/silicon module, and the outer shell contains the necessary apparatus for anchoring the implant. In a preferred embodiment, the outer shell may be formed with existing plastic injection technologies suitable for medical implantation. A coating, preferably of silicone, parylene and/or polymers provides a non-thrombogenic exterior for the biologic environment.

The implant may be located in various places depending on the blood pressure measurement of interest. For chronic heart failure the end-diastolic pressure or mean left atrium pressure may be of most importance, and therefore the left chambers of the heart or immediately attaching vessels may be preferred locations. Because the number of implants is not practically limited by the technology, multiple locations for blood pressure and/or other physiologic parameter measurements are easily established, including all chambers of the heart, major arteries and appendages. The atrial septum is the preferred embodiment, Figure 5, since, embedding the module in the atrial septum does not significantly impede blood flow and thus minimize the thrombogenic effect of flow turbulence caused by this volume.

The implant may be modified with anchoring methods found on devices already used for implantation. Devices such as septal occluders, pacemaker leads, left atrial appendage occluders, etc., may be used as carriers for the current invention. Devices have been made and approved by the FDA to occlude atrial septum defects (a septal occluder) and other vascular

holes. An umbrella structure **14,** Figure 5, may be folded inside a catheter for delivery and then expanded for implantation. In a preferred embodiment, the present invention may be anchored to the septum with similar techniques, as shown in Figure 5. An important aspect of this preferred embodiment is that the majority of the implantable sensing device is located in the right side of the heart, with minimum protrusion in the left side of the heart. This embodiment will greatly reduce the thrombogenicity.

Pacemaker leads have a well-established history for implantation methods, and similar techniques are possible for the current invention. A screw **13** (Figure 4) or barb may be used to attach the implant to a heart or vessel wall. In the first package option shown in Figure 4, a screw **13** may be molded into the device shell **26**, and screwed into the ventricle wall so that that the screw buries below the wall surface. In addition, the package may have mesh **25** attached to the device to promote tissue growth and anchoring.

A second package option can be attached with a metal tine or barb placed with a catheter. These devices work well in tribeculated areas of the heart, and therefore are used often for implanting pacing leads in the right ventricle. Clips or expanding probes may also be used, both of which would penetrate the heart or vessel wall slightly.

Devices have been made and approved by the FDA to occlude atrial septum defects (a septal occluder) and other vascular holes. An umbrella structure may be folded inside a catheter for delivery and then expanded for implantation, shown Figure 5. In the preferred embodiment, the present invention is anchored to the septum with similar techniques. An important aspect of this preferred embodiment is that the majority of the implantable sensing device is located in the right side of the heart, with minimum protrusion in the left side of the heart. This embodiment will greatly reduce the thrombogenicity.

Note that in addition to sensing physiologic parameters, the described system could be augmented with various actuation functions. In such case, the implant device would be augmented with any of various actuators, including but not limited to: thermal generators; voltage or current sources, probes, or electrodes; drug delivery pumps, valves, or meters; microtools for localized surgical procedures; radiation-emitting sources; defibrillators; muscle stimulators; pacing stimulators.

The foregoing disclosure includes the best mode devised by the inventors for practicing the invention. It is apparent, however, that several variations in the apparatuses and methods of the present invention may be conceivable by one skilled in the art. Inasmuch as the foregoing disclosure is intended to enable one skilled in the pertinent art to practice the instant invention, it should not be construed to be limited thereby, but should be construed to include such aforementioned variations.